

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

BARRY C. HONIG, GRQ CONSULTANTS, INC., GRQ CONSULTANTS, INC. 401K, GRQ CONSULTANTS, INC. ROTH 401K FBO BARRY HONIG, GRQ CONSULTANTS, INC. ROTH 401K FBO RENEE HONIG, HS CONTRARIAN INVESTMENTS, LLC, ROBERT S. COLMAN, and ROBERT S. COLMAN TRUST UDT 3/13/85,

Plaintiffs,

v.

JOHN DAVID HANSEN and GREGORY P. HANSON,

Defendants.

Case No. 1:20-cv-05872-AKH (Lead Case)

GRANDER HOLDINGS, INC., GRANDER HOLDINGS, INC. 401K PSP, BRAUSER FAMILY TRUST 2008, MICHAEL BRAUSER, DANIEL BRAUSER, BENJAMIN BRAUSER, GREGORY BRAUSER, and JOSHUA BRAUSER,

Plaintiffs,

v.

JOHN DAVID HANSEN and GREGORY P. HANSON,

Defendants.

Case No. 1:20-cv-08618-AKH

**COLMAN-HONIG PLAINTIFFS' MEMORANDUM OF LAW
IN SUPPORT OF MOTION FOR LEAVE TO FILE AN AMENDED
COMPLAINT PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 15**

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Pursuant to Federal Rule 15(a) of the Federal Rules of Civil Procedure and Local Civil Rule 6.3, Plaintiffs Robert S. Colman, Robert S. Colman Trust UDT 3/13/85, Barry C. Honig, GRQ Consultants, Inc., GRQ Consultants, Inc. 401K, GRQ Consultants, Inc. Roth 401K FBO Barry Honig, GRQ Consultants, Inc. Roth 401K FBO Renee Honig and HS Contrarian Investments, LLC, (collectively, the “**Colman-Honig Plaintiffs**”), respectfully submit this memorandum of law in support of their Motion for Leave to File a Fifth Amended Complaint (“**Motion**”).

PRELIMINARY STATEMENT

On April 27, 2022, this Court found that the Colman-Honig Plaintiffs’ Fourth Amended Complaint sufficiently alleged all necessary elements for two securities fraud causes of action arising under the California Corporations Code (the “**April 27, 2022 Order**”). Specifically, the Court found that the Colman-Honig Plaintiffs sufficiently alleged that Defendants induced plaintiffs to purchase securities of MabVax Therapeutics Holdings, Inc. (“**MabVax**”) through the issuance of materially misleading statements that omitted to disclose that patients in MabVax’s Phase I clinical trial had suffered significant adverse events which caused suspension of the trial. The Court’s April 27, 2022 Order allows the Colman-Honig Plaintiffs to proceed with its case against Defendants for specified statements made during calendar year 2018.

After the prior complaint was filed in November 2021, and while Defendants’ motion to dismiss was pending, new, previously non-public evidence came to light which revealed that the adverse events were disturbingly numerous and Defendants’ deception about them started earlier – during 2016. The information mainly came from the depositions of two former high-level MabVax officers, including Defendant David Hansen, taken on January 17 and April 28, 2022, in the separate lawsuit that MabVax initiated in California. Those depositions revealed that **over two hundred** adverse events were suffered by patients in MabVax’s clinical trial, including at

least forty that rose to the level of “severe” (potentially requiring hospitalization) or “life threatening.” The adverse events began surfacing in mid-2016, then continued through 2017 and into 2018.

Defendants did not disclose this material information to investors. To the contrary, even though they knew that most patients in the clinical trial suffered at least some adverse events, and approximately half of patients experienced severe or life-threatening adverse events, during 2016 and 2017 Defendants caused MabVax to make over a dozen statements asserting, falsely or misleadingly, that the treatment was “safe” and “well-tolerated” by the “majority” of patients. These representations were blatantly untrue, and were made for the same purpose as Defendants’ 2018 misstatements: to induce investors, including the Colman-Honig Plaintiffs, to purchase millions of dollars of MabVax securities.

Based on this newly discovered evidence, the Colman-Honig Plaintiffs wish to amend their complaint to allege additional fraudulent statements made by the Defendants during late 2016 and 2017, and purchases of MabVax securities made in reliance upon those statements. These “new” statements are alleged to be materially untrue for substantially the same reason as those statements which the Court previously found were adequately alleged to be false. Until the new evidence was gleaned over the past few months, however, the Colman-Honig Plaintiffs were not aware of the factual falsity of these additional statements. Concurrently with this motion, the Colman-Honig Plaintiffs submit a proposed Fifth Amended Complaint (“**5thAC**”) which identifies the additional misstatements, and explicitly details the reasons why each statement was materially untrue when made. The proposed 5thAC also eliminates prior factual allegations

which the Court has deemed deficient.¹

Federal Rule of Civil Procedure 15 and Second Circuit precedent direct that leave to amend should be freely granted. There is no reason to deviate from that principle here. This case is at an early stage; discovery is just beginning. The Colman-Honig Plaintiffs do not seek to add any new causes of action, legal claims or legal theories. The Court already has found that they have plausibly alleged that Defendants made misstatements concerning adverse events encountered by patients in MabVax's clinical trial that caused MabVax to shut down the clinical trial; the Colman-Honig Plaintiffs now propose to simply add similar misstatements that occurred earlier in time. The new factual allegations are based upon newly discovered facts that MabVax never disclosed to investors, and that were obtained only as the result of depositions taken in another proceeding within the past few months.

As the Court observed from the bench during its February 24, 2022 hearing, "Sometimes it takes a long time to get [a complaint] right."² This is one of those times, as Defendants purposefully concealed the poor safety data that arose during MabVax's clinical trial, which eventually led to the suspension of that trial and the collapse of MabVax itself. The Colman-Honig Plaintiffs respectfully ask the Court to grant them leave to file their Fifth Amended Complaint.

¹ See, e.g., April 27, 2022 Order at pp. 9-10. Specifically, the proposed 5thAC eliminates prior allegations concerning Defendants' statements about the reasons why the second tranche of a loan from Oxford Finance LLC to MabVax was not funded, and also eliminates prior allegations concerning Defendants' alleged interference with an agreement between MabVax and certain investors to enact corporate pay cuts.

² Transcript from February 24, 2022 Hearing, at 42:20-21.

I. PROCEDURAL HISTORY

A. The Original Complaint and Prior Amendments

Plaintiffs filed their original complaint on July 28, 2020 [Dkt. 1], and pursuant to Federal Rules of Civil Procedure Rule 15(a)(1)(B) filed a First Amended Complaint (“FAC”) on October 2, 2020. [Dkt. 34]. On November 20, 2020, the Court consolidated this case with civil case number 20-cv-8618 for purposes of discovery. [Dkt. 52]. Defendants moved to dismiss the complaints in both actions on November 30, 2020. [Dkt. 57].

On August 9, 2021, this Court issued an order directing Plaintiffs to amend the FAC’s jurisdictional allegations. [Dkt. 103]. In response, Plaintiffs filed a Second Amended Complaint (the “SAC”) that both revised jurisdictional allegations, and also amended a number of merits-related allegations of the FAC. [Dkt. 104]. Defendants filed a motion to strike the SAC because it contained amendments beyond only the jurisdictional allegations [Dkt. 106]. The Court granted that motion to strike [Dkt. 111], necessitating the filing of a Third Amended Complaint on September 16, 2021. [Dkt. 112].

On October 6, 2021, the Court issued an Order Granting Defendants’ Motion to Dismiss the Third Amended Complaint [Dkt. 113], and two days later issued an Amended Order directing the Clerk to close civil cases 20-cv-5872 and 20-cv-8618 and grant judgment to the Defendants. [Dkt. 114]. The Clerk entered Judgment on October 12, 2021. [Dkt. 115].

Plaintiffs requested leave to amend, and on November 24, 2021, the Court granted leave to amend and vacated the prior judgment. [Dkt. 121]. Plaintiffs filed their Fourth Amended Complaint on November 30, 2021. [Dkt. 122]. Defendants again moved to dismiss, on December 22, 2021. [Dkt. 123]. The Court heard lengthy oral argument, in person, on February 24, 2022. [Dkt. 145].

B. The Court Partially Denies and Partially Grants Defendants’ Motion to Dismiss the Fourth Amended Complaint, Finding That Plaintiffs Adequately Alleged Two Fraud-Based Causes of Action.

On April 27, 2022, the Court entered an order granting in part and denying in part the Defendants’ motion to dismiss. [Dkt. 147] (the “**April 27, 2022 Order**”). The Court specifically found that the Colman-Honig Plaintiffs’ Fourth Amended Complaint sufficiently alleged two causes of action for securities fraud arising under Section 25400(d), *et seq.* of the California Corporations Code, to the extent that those causes of action were based upon Defendants’ statements concerning MabVax’s clinical trial. The Fourth Amended Complaint alleged that MabVax statements made during 2018 were materially misleading as to the progress of the Phase 1 clinical trial, because they did not disclose that patients in the trial had suffered one or more adverse events that caused the trial to be suspended. Instead of disclosing that negative information, Defendants caused MabVax to issue statements in 2018 touting “positive” data from the trial and soliciting funding for further patient enrollment. The Court specifically found that the complaint plausibly alleged material misrepresentations, Defendants’ scienter, and loss causation under a “materialization of the risk” theory:

Plaintiffs allege that if the adverse event and trial enrollment suspension had been disclosed earlier, the disclosure would have prevented Defendants from securing further funding and ruined the Company. Defendants withheld this information from the market, enabling them to solicit further investments from Plaintiffs. Indeed, Plaintiffs invested in May 2018 based upon the reported strength of the progress in the clinical trials and without knowledge of the enrollment suspension. In October 2018, however, the Company issued a corrective disclosure, which revealed the adverse event and suspension. This caused Defendants to be unable to raise further funds and forced MabVax into bankruptcy. Thus, when Mab Vax issued its corrective disclosure, the risk that Defendants sought to conceal (that Mab Vax did not have a viable product) materialized, causing the company to fail and rendering Plaintiffs’ investments worthless.

[April 27, 2022 Order at p. 13]. The Court also partially granted Defendants’ motion, dismissing with prejudice the Colman-Honig Plaintiffs’ claims that were based upon statements that the

Defendants made concerning the reasons why the second tranche of a loan from Oxford Finance LLC to MabVax was not funded. [*Id.* at pp. 9-10]. The Court summed up its decision as follows:

I find that Plaintiffs' claims based upon the Oxford Loan statements are not actionable and dismiss them with prejudice. However, I find that Plaintiffs' claims based upon Defendants' failure to disclose the adverse event and trial enrollment suspension are actionable but only as to the investments made after the misleading press releases but prior to the corrective disclosure on October 15, 2018.

[*Id.* at p. 14].

C. Recently Discovered Evidence Reveals That Defendants Made Materially False Statements Concerning MabVax's Clinical Trial Starting As Early As November 2016.

After the Fourth Amended Complaint and Defendants' motion to dismiss it were filed, defendant David Hansen was deposed on January 17, 2022 in connection with the lawsuit initiated by MabVax in California state court.³ During that deposition Mr. Hansen revealed, among other facts, that MabVax's antibody treatment caused at least four patients in the Clinical Trial to suffer a serious lung condition called pneumonitis, that the incidents of pneumonitis began surfacing in early 2017, and that the prevalence of pneumonitis is what caused MabVax to later suspend the trial in 2018. None of those facts had previously been disclosed publicly by Defendants or MabVax.⁴

After defendant Hansen provided that surprising testimony, the deposition of MabVax's former Vice President of Pharmaceutical Development, Paul Maffuid, was taken on April 28, 2022. Mr. Maffuid provided significant additional detail about the pneumonitis incidents first revealed by defendant Hansen, and also disclosed material information concerning adverse events that patients in the clinical trial suffered as early as 2016.

³ *MabVax Therapeutics Holdings, Inc. v. Honig, et al.*, Superior Court of California, County of San Diego case no. 37-2019-00018398-CU-SL-CTL.

⁴ Plaintiffs' counsel Robert Weber previewed some of this newly discovered information to the Court during its February 24, 2022 hearing. [See Dkt. 145, at 32:17-35:16].

D. The Proposed Fifth Amended Complaint.

Based primarily upon the newly discovered deposition evidence, the Colman-Honig Plaintiffs have drafted a proposed Fifth Amended Complaint which identifies 11 separate disclosures that Defendants made from November 16, 2016 through February 6, 2018 that were materially false or misleading. The Colman-Honig Plaintiffs wish to add these 2016 and 2017 statements to the 2018 statements which the Court already has found sufficient to provide the basis for two causes of action. A copy of the Colman-Honig Plaintiffs' proposed Fifth Amended Complaint is submitted concurrently as Exhibit A to the Declaration of Robert D. Weber in support of the instant motion. Also attached, as Exhibit B, is a "redline" identifying all additions and deletions of material from the currently operative Fourth Amended Complaint, to the proposed Fifth Amended Complaint.

The new factual allegations may be summarized as follows: MabVax began enrolling patients in its clinical trial in March 2016. Thirty-two patients participated in the first part of the clinical trial during which they were administered a regimen of MabVax's antibody for a period of weeks that varied from patient to patient. Almost from the start, those thirty-two patients suffered a disturbingly high number of adverse events, including liver damage, hyperglycemia, hypoalbuminemia, anemia, vomiting and nausea. Between April 2016 and May 2017, those 32 patients suffered an astronomical 172 adverse events in all; at least 27 of those adverse events were graded "Grade 3 – Severe" (which indicates significant symptoms requiring hospitalization or invasive intervention) or "Grade 4 – Life-Threatening." The vast majority of patients (over 80%) suffered adverse events, and approximately half the patients suffered "severe" or "life threatening" events.

MabVax initiated a second part of its clinical trial in late 2016, in which its antibody was combined with a medically standard chemotherapy. The safety results were even worse. During late 2016 and early January 2017, the first three patients encountered 24 adverse events, with seven of those adverse events graded Grade 3 (Severe) or Grade 4 (Life Threatening). Those patients' reactions were so bad that their treatment was discontinued, and MabVax decided to reduce by a factor of eight (from 1 mg/kg down to 0.125 mg/kg) the antibody dose administered to future patients. That did not resolve the safety issues. In early 2017, two of the next three patients developed Grade 3 (Severe) pneumonitis, an inflammation of lung tissue that had the potential to cause irreversible lung damage. Another patient in a subsequent cohort suffered Grade 4 (Life Threatening) pneumonitis in early 2018. Incidents of pneumonitis associated with standard chemotherapy are rare (studies indicate it is less than 5% of patients), so for three of six patients to encounter the serious condition when administered standard chemotherapy in combination with an already-reduced dosage of MabVax's antibody was alarming. When a fourth patient developed pneumonitis in 2018, MabVax was forced to suspend the trial.

But while Defendants knew most of these facts as they arose, they did not disclose that information to Plaintiffs. To the contrary, Defendants caused MabVax to issue multiple public statements in November 2016, and February, March, May, July, September and October 2017, variously claiming that the interim trial results were "positive," that "safety . . . has been established at three dose levels," and that the treatment as administered to certain patients was "well tolerated." Those statements were materially false or misleading. And Plaintiffs relied on them when purchasing MabVax securities starting in May 2017, and continuing through May 2018.

In addition to the new allegations concerning Defendants' false statements in 2016 and

2017, the Colman-Honig Plaintiffs’ proposed Fifth Amended Complaint also eliminates prior allegations concerning the Oxford Finance loan, and allegations concerning Defendants’ alleged interference with an agreement to enact corporate pay cuts, both of which the Court previously ruled were deficient.

II. LEAVE TO AMEND SHOULD BE GRANTED

The Federal Rules of Civil Procedure provide that courts “should freely give leave” to amend a complaint “when justice so requires.” Fed. R. Civ. P. 15(a)(2). The Supreme Court has articulated the following criteria concerning Rule 15(a) motions:

If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits. In the absence of any apparent or declared reason – such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc. – the leave sought should, as the rules require, be “freely given.”

Foman v. Davis, 371 U.S. 178, 182 (1962)). Amendments are favored because they tend to accommodate the Second Circuit’s oft-repeated “strong preference for resolving disputes on the merits.” *Williams v. Citigroup Inc.*, 659 F.3d 208, 212-13 (2d Cir. 2011); *see also Porat v. Lincoln Towers Cmty. Ass’n*, 464 F.3d 274, 276 (2d Cir. 2006) (“[T]his Circuit strongly favors liberal grant of an opportunity to replead after dismissal of a complaint under Rule 12(b)(6).”).

The Second Circuit, citing *Foman*, has stated that “it is rare that such leave should be denied,”⁵ and has additionally held that leave to amend “should not be denied unless there is evidence of undue delay, bad faith, undue prejudice to the non-movant, or futility.” *Milanese v. Rust-Oleum Corp.*, 244 F.3d 104, 110 (2d Cir. 2001) (citing *Foman* and reversing district court’s denial of leave to amend). The party opposing a motion to amend bears the burden of proof. *See*

⁵ *Ricciuti v. N.Y.C. Transit Auth.*, 941 F.2d 119, 123 (2d Cir. 1991) (internal citation omitted).

Bangkok Crafts Corp. v. Capitolo Di San Pietro in Vaticano, 2005 WL 1706490, at *3 (S.D.N.Y. July 21, 2005).

Here, there is no evidence of undue delay, bad faith, or undue prejudice, nor would the requested amendments be futile. As noted above, Plaintiffs learned the core facts supporting its proposed amendments only recently, during depositions of former MabVax officers in January and April 2022. About a month after first discovering some of this information, Plaintiffs' counsel informed the Court (and opposing counsel) of the Colman-Honig Plaintiffs' desire to amend.⁶ Plaintiffs have not delayed nor acted in bad faith in now seeking these amendments. In any event, "[m]ere delay . . . absent a showing of bad faith or undue prejudice, does not provide a basis for a district court to deny the right to amend." *Block v. First Blood Assocs.*, 988 F.2d 344, 350 (2d Cir. 1993) (citing *State Teachers Retirement Bd. v. Fluor Corp.*, 654 F.2d 843, 856 (2d Cir.1981)).

Defendants cannot show that amendment at this stage of the proceedings would result in undue prejudice. "The party opposing the motion for leave to amend has the burden of establishing that an amendment would be prejudicial." *Fariello v. Campbell*, 860 F. Supp. 54, 70 (E.D.N.Y. 1994) (citing *Panzella v. Skou*, 471 F. Supp. 303, 305 (S.D.N.Y.1979)). Undue prejudice depends on whether the new aspects of the proposed pleading would "(i) require the opponent to expend significant additional resources to conduct discovery and prepare for trial; (ii) significantly delay the resolution of the dispute; or (iii) prevent the plaintiff from bringing a timely action in another jurisdiction." *Monahan v. New York City Dep't of Corrs.*, 214 F.3d 275, 284 (2d Cir. 2000) (quoting *Block*, 988 F.2d at 350). Those factors are not present here. This action is in an early stage; as of the date of this filing, the Court has not even held an initial

⁶ See Transcript of February 24, 2022 hearing. [Dkt. 145, at 35:9-16].

conference or set a discovery schedule. There has been no real delay in making this Motion, as the new evidence upon which the proposed 5thAC is based surfaced only very recently.

Discovery is just commencing now. Neither side has yet to serve any discovery requests.

Defendants have ample time to tailor their discovery requests to address all statements which the Colman-Honig Plaintiffs allege to be false, including the new ones identified in the 5thAC.

Adding these statements to the action does not even change who the likely witnesses or document custodians will be; the same people with knowledge germane to the 2018 alleged misstatements have knowledge regarding the 2016 and 2017 alleged misstatements. Furthermore, “the adverse party’s burden of undertaking discovery, standing alone, does not suffice to warrant denial of a motion to amend a pleading.” *United States v. Continental Ill. Nat’l Bank & Trust Co.*, 889 F.2d 1248, 1255 (2d Cir. 1989). In any event, the burden of establishing “undue prejudice” is not satisfied by assertions that an amendment will require the expenditure of additional time, effort, or money. *Block*, 988 F.2d at 351.

There also can be no suggestion that amending the complaint to add some additional misstatements would be futile. An amendment is futile if it would not withstand a motion for dismissal under Federal Rule of Civil Procedure 12(b)(6). *Bangkok Crafts Corporation*, 2005 WL 1706490, at *3. Here, the additional fraudulent statements that Plaintiffs wish to add to the complaint are essentially identical in character to other statements which have survived a prior 12(b)(6) motion, and which the Court has found “plausibly allege a material representation.” [April 27, 2022 Order at 11].

Lastly, while Plaintiffs believe that Rule 15(a) provides all the authority needed to allow amendment, Plaintiffs recognize that the Court’s April 27, 2022 Order contained a catch-all statement at its conclusion granting Defendants’ prior motion to dismiss with prejudice “as to all

remaining Plaintiffs and claims” beyond investments made on May 2, 8 or 11. To the extent that granting leave to file the proposed Fifth Amended Complaint might be construed as seeking reconsideration of that aspect of the April 27, 2022 Order, Plaintiffs respectfully suggest that reconsideration is warranted under these circumstances where Plaintiffs obtained newly discovered evidence as recently as April 28, 2022, as described above. *See, e.g., Virgin Atl. Airways, Ltd. v. Nat’l Mediation Bd.*, 956 F.2d 1245, 1255 (2d Cir. 1992) (“the availability of new evidence” is one of the major, long-established grounds for granting reconsideration); *Haider v. Lyft, Inc.*, 2022 WL 1500673, at *1 (S.D.N.Y. May 11, 2022) (same).

CONCLUSION

The Colman-Honig Plaintiffs respectfully request that the Court grant their Motion for leave to amend their complaint in accordance with the concurrently filed Proposed Fifth Amended Complaint, and, to the extent required, reconsider the April 27, 2022 Order to the extent that it ordered a with-prejudice dismissal.

Dated: New York, New York
May 25, 2022

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